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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,272	07/30/2001	Mark Seaver	N.C. 80,218	8684

7590 02/13/2004

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,272

Applicant(s)

SEAVER ET AL.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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No references were found with the file, all the listed US Patents have been considered but the foreign documents are not readily available to the examiner.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over .

Mansour (4,693,972) entitled "Composition and Methods for Rapid Detection of Microorganisms in Clinical Samples" teaches in column 2 fluorescence microscopy has been utilized to selectively stain bacteria in blood samples. These methods stain platelets as well however. In the present invention microorganisms are detecting by staining with a fluorescent dye after lysis of other components such as blood cell components. In column 3 last paragraph bridging to column 4, the debris from lysis has a maximum particle size of less than about 0.2 microns but the lysis must not be so severe as to lyse the microorganisms to be detected. Various Tween products are discussed in column 4 for lysing. An number of standard fluorescent dyes are disclosed in column 4. In column 5 lines 14-16, the stained cells may be separated from the sample before observation by any conventional separation technique.

The claims differ from Mansour in that they are directed to determining bacteria in a sample containing platelets specifically whereas Mansour teaches blood samples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the same method taught by Mansour to determine bacteria in platelets because the claims as written are directed to "a sample containing platelets" which reads on whole blood, and further one would expect the method of Mansour would have the same function in determining platelet samples as it would blood samples. Of course blood samples contain platelets and lysing and staining platelets are well known in this art. No criticality is seen in the degree of lysis claimed or

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concentrations of reagents. To employ automated apparatus in place of not automated apparatus is not novel.

Claims 2-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each instance applies in all occurrences.

In claim 2 and all occurrences, dependent claims should begin with a definite article. In claim 3, "destroying" is queried in context. In claims 6 and 7, abbreviations should be spelled out in the first instance in the claims. And trademark names are inappropriate in claims, generic terminology is suggested. The preamble of claim 16 is directed to ascertaining a presence but the last step determines the presence.

The Abstract of the Disclosure is objected to because it is more than one paragraph. Correction is required. See M.P.E.P. § 608.01(b).

The use of the trademarks Triton and Syto have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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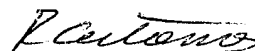
The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Zierdt (4,410,630) teaches lysis filtration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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